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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/609,346 | 06/26/2003 | Zailin Yu | ZYU-0603 | 1103 |

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EXAMINER

MERTZ, PREMA MARIA

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
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1646

DATE MAILED: 04/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/609,346

Applicant(s)

YU ET AL.

Examiner

Prema M. Mertz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1. Claims 1-11, 27-33, 40-41, are drawn to a nucleic acid encoding a fusion protein wherein the first nucleic acid encodes the amino acid sequence set forth in SEQ ID NO:12 and the second nucleic acid encodes the amino acid sequence set forth in SEQ ID NO:14, a vector, and a host cell, classified in Class 536, subclass 23.4.

Group 2. Claims 1-11, 27-33, 40-41, are drawn to a nucleic acid encoding a fusion protein wherein the first nucleic acid encodes the amino acid sequence set forth in SEQ ID NO:12 and the second nucleic acid encodes the amino acid sequence set forth in SEQ ID NO:16, a vector, and a host cell, classified in Class 536, subclass 23.4.

Group 3. Claims 1-11, 27-33, 40-41, are drawn to a nucleic acid encoding a fusion protein wherein the first nucleic acid encodes the amino acid sequence set forth in SEQ ID NO:12 and the second nucleic acid encodes the amino acid sequence set forth in SEQ ID NO:18, a vector, and a host cell, classified in Class 536, subclass 23.4.

Group 4. Claims 1-11, 27-33, 40-41, are drawn to a nucleic acid encoding a fusion protein wherein the first nucleic acid encodes the amino acid sequence set forth in SEQ ID NO:12 and the second nucleic acid encodes the amino acid sequence set forth in SEQ ID NO:20, a vector, and a host cell, classified in Class 536, subclass 23.4.

Group 5. Claims 1-11, 27-33, 40-41, are drawn to a nucleic acid encoding a fusion protein wherein the first nucleic acid encodes the amino acid sequence set forth in SEQ ID

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NO:12 and the second nucleic acid encodes the amino acid sequence set forth in SEQ ID NO:22, a vector, and a host cell, classified in Class 536, subclass 23.4.

Group 6. Claims 12-14, 27-33, 40-41, are drawn to a nucleic acid encoding a fusion protein HSA-IL-11 of amino acid sequence set forth in SEQ ID NO:2, a vector, and a host cell, classified in Class 536, subclass 23.4.

Group 7. Claims 12-14, 27-33, 40-41, are drawn to a nucleic acid encoding a fusion protein HSA-IL-3 of amino acid sequence set forth in SEQ ID NO:4, a vector, and a host cell, classified in Class 536, subclass 23.4.

Group 8. Claims 12-14, 27-33, 40-41, are drawn to a nucleic acid encoding a fusion protein HSA-EPO of amino acid sequence set forth in SEQ ID NO:6, a vector, and a host cell, classified in Class 536, subclass 23.4.

Group 9. Claims 12-14, 27-33, 40-41, are drawn to a nucleic acid encoding a fusion protein HSA-GCSF of amino acid sequence set forth in SEQ ID NO:8, a vector, and a host cell, classified in Class 536, subclass 23.4.

Group 10. Claims 12-14, 27-33, 40-41, are drawn to a nucleic acid encoding a fusion protein HSA-GMCSF of amino acid sequence set forth in SEQ ID NO:10, a vector, and a host cell, classified in Class 536, subclass 23.4.

Group 11. Claims 34-39 are drawn to a recombinant polypeptide of amino acid sequence set forth in SEQ ID NO:2, classified in Class 530, subclass 350.

Group 12. Claims 34-39, are drawn to a recombinant polypeptide of amino acid sequence set forth in SEQ ID NO:4, classified in Class 530, subclass 350.

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Group 13. Claims 34-39 are drawn to a recombinant polypeptide of amino acid sequence set forth in SEQ ID NO:6, classified in Class 530, subclass 350.

Group 14. Claims 34-39 are drawn to a recombinant polypeptide of amino acid sequence set forth in SEQ ID NO:8, classified in Class 530, subclass 350.

Group 15. Claims 34-39 are drawn to a recombinant polypeptide of amino acid sequence set forth in SEQ ID NO:10, classified in Class 530, subclass 350.

Group 16. Claims 42-43 are drawn to a composition comprising a combination of HSA/IL-11 fusion and HSA/EPO fusion, classified in Class 514, subclass 2.

Group 17. Claims 42, 44 are drawn to a composition comprising a combination of HSA/IL-3 fusion and HSA/EPO fusion, classified in Class 514, subclass 2.

Group 18. Claims 42, 45 are drawn to a composition comprising a combination of HSA/IL-3 fusion and HSA/GCSF fusion, classified in Class 514, subclass 2.

Group 19. Claim 46 is drawn to a method of treatment by administering a fusion protein of HSA and CPSF, classified in Class 514, subclass 2.

Group 20. Claims 47-48 are drawn to a method of treatment by administering a combination of HSA/IL-11 fusion and HSA/EPO fusion, classified in Class 514, subclass 2.

Group 21. Claims 47-48 are drawn to a method of treatment by administering a combination of HSA/IL-3 fusion and HSA/EPO fusion, classified in Class 514, subclass 2.

Group 22. Claims 47-48 are drawn to a method of treatment by administering a combination of HSA/IL-3 fusion and HSA/GCSF fusion, classified in Class 514, subclass 2.

Group 23. Claims 49-50 are drawn to a kit comprising a combination of HSA/CPSF fusion and a different HSA/CPSF fusion, classified in Class 435, subclass 810.

Applicants are advised that in claim 6, the multiple elements recited therein, do not share a common technical feature, which is based on a common property or special technical feature not found in the prior art. These compounds are independent and distinct chemical compounds lacking either a common structural property which distinguishes them as a group from structurally related compounds of the prior art or which provides them with a common utility which is lacking from prior art compounds.

Claims 1-3 link(s) inventions [1] -[5]. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-3. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim 42 links inventions [16] -[18]. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim 42. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional

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application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim 47 links inventions [20] -[22]. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim 47. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons:

Inventions 1-18, 23, are independent and distinct, each from the other, because they are products, which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention, which cannot be exchanged. The polynucleotides of inventions 1-10, can be used to make hybridization probes or can be used in

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gene therapy as well as in the production of the specific proteins of interest. The proteins of inventions 11-18 can be used as probes, or used therapeutically or diagnostically, e.g. in screening. Each of the polynucleotides of inventions 1-10 can be used to produce specific polypeptides. The polynucleotide of Group I can only be used to produce the fusion protein of amino acid sequence set forth in SEQ ID NO:12 and 14, but not the fusion protein of the other Groups.

Inventions 6-10 and 11-15 are related as process of making and products made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case each of the proteins can be prepared by materially different processes, such as by chemical synthesis.

Inventions 3 and 9 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product of invention 3 can also be used as an antigen in the production of specific antibodies.

Inventions 11-15 and 19-22 are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P.

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§ 806.05(h)). In the instant case the products of inventions 11-14 can also be used as an antigens in the production of specific antibodies.

Inventions 1-10, 19-23 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions 1-2 and 9-12 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons:

Inventions 19-22 are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different classification, different starting materials, process steps and goals. For example, invention 20 requires search and consideration of therapeutic efficacy of administering a combination of fusion proteins HSA/IL-11 and HAS/EPO, which combination is not required by the methods of any of the other Groups.

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Therefore, a search and examination of all 4 methods in one patent application would result in an undue burden.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

2. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

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Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Prema Mertz Ph.D., J.D.

Primary Examiner

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April 17, 2006